

P R E S E N T E D A T

WORLD CONGRESS OF ENDOUROLOGY

■ A N N U A L C O N G R E S S ■

September 12–16, 2017 ■ Vancouver, Canada

Presentation Title: **COMPARATIVE EVALUATION OF TISSUE DAMAGE INDUCED BY
ULTRASOUND AND IMPACT DUAL MODE ENDOSCOPIC LITHOTRIPSY
VERSUS CONVENTIONAL SINGLE MODE ULTRASOUND LITHOTRIPSY**

Author Block: **MJ Bader, W Khoder, M Seitz, F Strittmatter, A Alghamdi, C Stief**
– UroClinic München and Department of Urology, University of Munich, Germany

Introduction and Objective

The EMS LithoClast™ Trilogy, a combined ultrasonic / impact lithotripter, was compared to the established ultrasound lithotripter Storz Calculon™. The safety test simulated the accidental direct contact between lithotripter probes and the urothelium which can occur when sliding off a stone during lithotripsy or drilling through a stone.

The purpose of this study was to investigate the tissue safety of a new ultrasound and impact dual mode lithotripsy transmitted through a single probe in an in vivo animal model.

Materials and Methods

Testing was performed in pigs on bladder tissues. Six female pigs (German Landrace) were allocated into 2 groups. Cystoscopic access to the pig bladder was established through a conventional cystoscope with straight working channel. The bladder tissue was exposed to direct lithotripter probe contact at maximum power during 10 seconds to produce visible tissue lesions. Small and large diameter probes (1.5 / 3.4 re. 3.5 mm) were tested. Acute tissue trauma was evaluated using a scoring model. After 7 days, all animals were sacrificed, necropsied and examined post mortem. Histological examinations of the urinary bladder were performed with each animal. The study was performed under a GLP compliant protocol and approved by the federal ethical committee of Bavaria, Germany.

Results

Irrespective of the lithotripter used, no systemic signs of toxicity were observed up to 7 days after the intervention. All lesions were set successfully and the acute and 7 days' post-op scoring could be performed in all animals. The evaluation did not reveal any relevant differences between the lesions set with either the small or large probes. Lack of intense leucocyte and other inflammatory cells infiltration confirmed the absence of aggressive systemic reactions and was confirmed as well by the absence of effects on hematological parameters. The documented minimal to mild vascular congestion at surgery as well as 7 days post-operatively is to be considered a normal finding in response to trauma. Histologically, signs of normal ongoing healing were observed on the urinary bladder mucosa.

Conclusions

The single probe combined ultrasonic and impact lithotripsy application with the LithoClast Trilogy device showed comparable tissue safety as conventional ultrasonic lithotripsy alone.

Reprinted with author's permission.

Bench Test results may not necessarily be indicative of clinical performance.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

All trademarks are the property of their respective owners.

**Boston
Scientific**
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

Ordering Information
1.888.272.1001

©2018 Boston Scientific Corporation
or its affiliates. All rights reserved.

URO-520112-AA FEB 2018